N THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **Ethicon Wave 8 cases listed in Exhibit A**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO EXCLUDE THE GENERAL CAUSATION OPINIONS OF DEFENSE EXPERT RICHARD MARCUS ELLKERMANN, M.D.

The proffered general causation/liability opinions of Richard Marcus Ellkermann, M.D., an expert for the Defendants, fail to pass the *Daubert* standard. Dr. Ellkermann is not qualified to discuss design issues regarding Defendants' Prolift/Gynemesh PS mesh products because he has extremely limited knowledge of the design process. Dr. Ellkermann also lacks the expertise to opine about the whether the warnings in those products' Instructions for Use ("IFU") were sufficient. As to methodology, Dr. Ellkermann's opinions are unreliable because he did not review any of the key documents that would have explained Ethicon's design procedures, because he reached opinions about the Prolift/Gynemesh PS's design without considering the design protocols, and because his complication rates are based on undocumented numbers. For all of these reasons, Dr. Ellkermann should be excluded from giving the two opinions that form the foundation of his analysis. As Dr. Ellkermann demonstrated during his deposition, he does not have the qualifications to give opinions about product design or about warnings, and he did

not use a reliable methodology in reaching his opinions. Dr. Ellkermann's opinions should also be excluded because he has not disclosed the basis for his opinions.

LEGAL STANDARD

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. On the issue of qualifications, "the district court must decide whether the expert has 'sufficient specialized knowledge to assist the jurors in deciding the particular issues in the case.'" *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999)).

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents "scientific knowledge," meaning that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury—i.e., whether it is relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). The relevance aspect of the inquiry is often discussed in terms of whether the expert's opinions "fit" the case. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

To meet the standard of reliability, the testimony "must be supported by appropriate validation—i.e., 'good grounds,' based on what is known. In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1383 (4th Cir. 1995).

There are five factors courts often consider, taken from the *Daubert* opinion, in assessing the reliability of expert testimony:

- (1) whether the testimony has been tested,
- (2) whether it has been published or exposed to peer review,
- (3) its rate of error,
- (4) whether there are standards and controls over its implementation, and
- (5) whether it is generally accepted.

See Cavallo v. Star Enterprise, 100 F.3d 1150, 1158 (4th Cir. 1996). However, "the factors discussed in *Daubert* were neither definitive, nor exhaustive." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

Courts should focus on expert witnesses' "principles and methodology, not on the conclusions that they generate." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). This is because "*Daubert* governs whether evidence is admitted, not how persuasive it must be to the factfinder." *Cavallo*, 100 F.3d at 1158.

ARGUMENT

There are several reasons that this Court should prohibit Dr. Ellkermann, a urogynecologist designated as a Defense expert, from giving opinions about the design of the Prolift/Gynemesh PS, or about product warnings. Dr. Ellkermann's report touches on several topics, and included are the following two general opinions:

- "Gynemesh PS in 2002 and Prolift in 2005 followed the use of the macroporous, type 1 Prolene mesh used in the TVT sling in the later 1990s and which had shown significant efficacy, safety and biocompatibility, desirability and benefits in a variety of studies in different cohorts and randomized controlled trials with follow up out to 17 years as discussed later."[1]

[1] Ellkermann Report for Ethicon Wave 8, attached as Exhibit C, at p. 6.

- "…I find the IFUs informative, helpful and adequate to the pelvic surgeon who would implant the device."[2]

The first bullet point does not use the word "design," but it clearly is an opinion about the product's design. The second opinion clearly goes to the issue of warnings. This Court should preclude Dr. Ellkermann from opining about either design issues or about warnings, for the reasons stated below.

I. Dr. Ellkermann should be precluded from giving design opinions because he did not review the key Ethicon documents related to product design, he has no knowledge about the design process, and he relies on personal complication rates that cannot be quantified.

Dr. Ellkermann's deposition testimony reveals that he is not qualified by "knowledge, skill, experience, training, or education" to give opinions about the design of medical devices such as the Prolift/Gynemesh PS. Dr. Ellkermann has never written a peer-reviewed journal article on the Prolift device.[3] He does not hold any kind of degrees or certification in chemical engineering or polymer chemistry.[4] Dr. Ellkermann has not done any bench research on polypropylene.[5]

Dr. Ellkermann has never personally designed a polypropylene medical device.[6] He does not hold any patents on medical devices.[7] His deposition further reveals that he does not have the necessary knowledge or education to give a reliable opinion about product design.

[2] *Id.* at 24.
[3] Ellkermann Dep., attached as Ex. B, 50:8-11.
[4] *Id.* at 51:23 – 52:6; 53:1-4.
[5] *Id.* at 54:14-19.
[6] *Id.* at 79: 9-18.
[7] *Id.* at 79:19-21.

A. Dr. Ellkermann largely ignored Ethicon's internal documents, and he demonstrated a complete lack of knowledge regarding the product design process.

This Court has previously recognized the importance of reviewing internal documents before giving opinions on design issues. *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *14 (S.D. W. Va. Apr. 24, 2015) (excluding expert's design opinions on design protocols because he had failed to review internal documents). In his deposition, Dr. Ellkermann testified that he has not reviewed the Ethicon's employee witness depositions and has not reviewed all of the company documents provided by Ethicon.[8] Dr. Ellkermann did not know what employees were involved in the design of the Prolift device and has not reviewed any of their deposition testimony.[9]

Because he did not review the relevant design documents, Dr. Ellkermann lacks the required knowledge to give a reliable opinion about the design of the Prolift/Gynemesh PS. For instance, Dr. Ellkermann conceded that he did not know if he reviewed the design history file for the Prolift but, if so, he does not recall what is in it:

> Q: Have you – in forming your opinions in this case, did you ever review the design history file for the Prolift?
>
> A: I may have at some point.
>
> Q: Is it on your reliance list?
>
> A: I don't know if I have reviewed that at some point.
>
> Q: Do you recall any of what's in the design history file, if you reviewed it?
>
> A: I don't.[10]

[8] Ellkermann Dep., Ex. B at 152:22 – 153:8.
[9] *Id.* at 87:8-19.
[10] *Id.* at 86:13-22.

As the name suggests, the design history file would include all of the information about the design of the product. The necessary components of a design history file are laid out in 21 C.F.R. § 820. *See* 21 C.F.R. § 820.1 ("The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use."). Ethicon research and design engineer Katrin Elbert, Ph.D., testified that the design history file is "the archive of all the documents that show us the history of the design of the product. It contains all of our design control documents, and it's also what we use to support regulatory submissions."[11] Dr. Ellkermann's failure to review or recall such important documents leaves him without a reasonable foundation for an opinion about the Prolift's product design.

Dr. Ellkermann also could not explain what a failure modes and effects analysis is, or what the purpose of it is. (*Id.* at 87:20 – 88:12). As discussed in the deposition of Ethicon medical director Charlotte Owens, the purpose of a design failure modes and effects analysis ("dFMEA") is to "review the potential risk associated with the design of the product."[12]

> Q. And when you say "associated with the design of the product," that means that when the product is in a woman's body and the product was manufactured completely consistent with the specifications, these are the things that could go wrong and harm a patient, correct?
>
> A. Correct.[13]
>
> Q. And you understood that it was required that you capture all of the different failure modes, all the things that could go wrong in the procedure, even if the doctor was properly trained and following the proper procedure, and the effects of those failure modes, the hazards that could occur, and the resulting harms, and you were supposed to capture all of them, correct?
>
> A. Yes, all that we could conceive of, yes.[14]

[11] Elbert Dep., Dec. 23, 2014, portions attached as Exhibit D, at 270:5-11.
[12] Owens Dep., Sept. 13, 2012, portions attached as Exhibit E, at 485:14-24.
[13] *Id.* at 485:25-486:7.
[14] *Id.* at 449:12-22.

Dr. Ellkermann should have reviewed these documents in forming his opinions about the design of the Prolift. But not only did he fail to review those documents, he could not even identify the purpose of the failure modes and effects analysis.

In addition, Dr. Ellkermann did not know what a DDSA is.[15] A DDSA is also an important component of the design process. The letters stand for "Device Design Safety Assessment."[16] Part of the DDSA form lists and rates hazards associated with the product.[17] Examples include biocompatibility hazards and hazards from use of the device.[18] Given that he did not know what a DDSA is, Dr. Ellkermann clearly did not review that information for the Prolift or Gynemesh PS.[19]

Dr. Ellkermann's lack of knowledge on these points demonstrates that he does not have the expertise necessary to opine about issues of product design, and his failure to review Ethicon's design documents in formulating his opinions was not a reliable methodology.

B. Dr. Ellkermann relies in part on supposedly low complication and high satisfaction rates from his own practice, yet he has produced no records on those points.

Dr. Ellkermann also should be excluded from giving design opinions because he relies in part on supposedly low complication rates from his practice; yet, these rates exist only in Dr. Ellkermann's head. Dr. Ellkermann testified that he has an "extremely low" complication rate of "probably less than 5 percent."[20] But Dr. Ellkermann has not provided the data from his purported database to support this figure and did not include this document on his reliance list.[21]

[15] Ellkermann Dep., Ex. B at 88:13-14.
[16] Owens Dep., Ex. E, at 497:20-23.
[17] *Id.* at 498:20-24.
[18] *Id.* at 498:25-499:12.
[19] Ellkermann Dep., Ex. B at 88:15-20.
[20] *Id.* at 15:13 – 16:3.
[21] *Id.* at 16:6-12.

Further, Dr. Ellkermann admitted upon further questioning that his estimate of 5 percent erosion rate is not specific to Prolift/Gynemesh.

> Q: Are the numbers that you're giving me, the 5 percent overall erosion and exposure, I think you called it a Class 1 complication, is that just Prolift/Gynemesh and Prolift+M or is that all of your pelvic organ prolapse meshes?
>
> A: I would say that that 5 percent, less than 5 percent erosion rate would apply to all transvaginal mesh that I've used in the last 15 years.
>
> Q: And have you ever broken it down between the Prolift and the Gynemesh PS and other vaginal –
>
> A: Not specifically.[22]

That testimony speaks for itself. Dr. Ellkermann is relying in part on complication rates from his own practice, and yet he has no foundation whatsoever for the claimed complication rates. He has not produced the purported database underlying these figures and admits that his estimate of a complication rate is not even limited to the product at issue. Plaintiffs have no reasonable way of testing the veracity of Dr. Ellkermann's numbers. Because there is no foundation for this testimony, Dr. Ellkermann should, at the very least, be prohibited from testifying about complication rates from his own practice. In addition, this testimony further demonstrates that there is no solid foundation for his general opinions about the safety of the Prolift design.

C. Dr. Ellkermann's testimony reveals a fundamental lack of understanding as to the process that companies go through in developing a medical device.

A third major problem with Dr. Ellkermann's opinions about product design is that he has no expertise in product development, and he did no analysis of the development work done by Ethicon with regard to the Prolift. Product development is a major component of product

[22] *Id.* at 20:8-11.

design. As stated in this Court's order on consolidation, the West Virginia Supreme Court has written:

> The term "unsafe" imparts a standard that the product is to be tested by what the reasonably prudent manufacturer would accomplish in regard to the safety of the product, having in mind the general state of the art of the manufacturing process, including design, labels and warnings, as it relates to economic costs, at the time the product was made.

(Mem. Op. & Order, *Mullins* Dkt. No. 38, at p. 2 (citing *Morningstar v. Black & Decker Mfg. Co.*, 253 S.E.2d 666, 667 (Syl. ¶ 5) (W. Va. 1979)). Other states have similar rules. *See, e.g.*, Tenn. Code Ann. § 29-28-102(8) (stating that a product is defective if a reasonably prudent manufacturer would not have placed it onto the market).

Dr. Ellkermann's testimony reveals that he has no expertise in the process that companies use in developing a new product.

> Q: Have you ever reviewed any of Ethicon's standing operating procedures related to design?
>
> A: I may have at some point.
>
> Q: Did any of those affect any of the opinions that you intend to offer in this case?
>
> A: They may.
>
> Q: How?
>
> A: Well, if I need to refresh my memory. But as we sit right here, they're not influencing any of my opinions because I'm not familiar with them.[23]

This testimony further illustrates Dr. Ellkermann's lack of knowledge as to the design process, as well as his failure to do the necessary research to inform himself in formulating his opinions. Consequently, he should be excluded from giving opinions about the design of the Prolift.

[23] Ellkermann Dep., Ex. B at 88:21 – 89:7.

II. Dr. Ellkermann has no expertise in the area of warnings and instructions, so those opinions should also be excluded.

Another area in which Dr. Ellkermann's opinions should be excluded is that of product warnings. He lacks the necessary experience and knowledge to offer information about warnings that would be helpful to the jury. In fact, Dr. Ellkermann cannot point to any treatise or document that states the industry standards governing warnings in a medical device.[24] Dr. Ellkermann indicates he "may" have reviewed the FDA's guidance for labeling in a medical device "at some point" but did not recall any specifics. He cannot recall reviewing the FDA's Blue Book memo.[25]

In fact, Dr. Ellkermann admitted that he has does not know what departments of medical device company are involved in creating warnings for an IFU and has not read testimony from any Ethicon employees regarding their position on what needs to be in the IFU for Prolift.[26] Dr. Ellkermann further testified that he had never drafted the IFU for a medical device, and that he had never worked on the warnings for a medical device or a prescription drug.[27] Finally, during his deposition Dr. Ellkermann admitted that he does not know by the process by which warnings are addressed by an IFU.

> Q: Earlier you stated it was their prerogative. Would you agree that that's their prerogative to put additional warnings that may not necessarily be required in the IFU they choose to do so?
>
> [Objection. Misstates.]
>
> A: Ethicon works with the FDA and the FDA will require companies to list things in the IFU. The process by which that takes place I can't specifically sit here and tell you now.

[24] Ellkermann Dep., Ex. B, at 62:11-22.
[25] *Id.* at 64:12 - 17.
[26] *Id.* at 65:1-13.
[27] *Id.* at 66: 5-16; 68:23 – 69:4.

> Q: Would you agree with me that if they want to, a company can list more warnings in their IFU than is required by law if they choose? Or do you know? [Objection. Foundation. Legal conclusion and way overbroad.}
>
> A: I don't know.[28]

Dr. Ellkermann's lack of familiarity with the warning process is instructive. In the *Bard* litigation, this Court precluded Dr. Shull from giving warnings opinions because he had testified that "I would not claim to be an expert in that area." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013), *amended on reconsideration in part* (June 14, 2013). This Court also wrote that Dr. Shull "is unqualified to testify on the specific issue of product warnings, as evidenced by his lack of familiarity with the process." *Id.; cf. Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 704 n.2 (S.D.W. Va. 2014). That same analysis applies here to Dr. Ellkermann, whose testimony demonstrates a lack of familiarity with the process of warnings. In addition to being unqualified to opine about warnings, Dr. Ellkermann has failed to demonstrate that his methodology in arriving at his warnings opinions was reliable.

III. Dr. Ellkermann should be precluded from giving any opinions on the Prolift/Gynemesh PS's product because he has not disclosed the basis for his opinions.

Dr. Ellkermann should be precluded from offering any opinions regarding the Prolift/Gynemesh PS's products because the basis for his conclusions has not been properly disclosed to Plaintiffs. Dr. Ellkermann's use of mesh products, and his qualifications as a urogynecologist do not, by themselves, uniquely qualify him to opine regarding the safety and efficacy of a medical device, any more than a licensed driver is qualified to opine about the safety of a vehicle based on how it feels when he drives it, or based on what he has observed when others drive it. Dr. Ellkermann testified that the foundation of his opinion that the Prolift is

[28] *Id.* at 98:14 – 99:6.

safe and effective is "my experience, my clinical experience, my communications with other colleagues, and my review of the literature of the years as well as specific review of the literature for preparations for the report."[29] A review of the literature does not provide sufficient basis for Dr. Ellkermann to offer a reliable design opinion, unless he can identify an appropriate standard that he applied. *See Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *14 (S.D. W. Va. Apr. 24, 2015) (finding that Dr. Schull had not reliably applied the principles learned through his experience and the literature to the facts of this case because he had not seen any standard operating procedures or design protocols for the development of the medical device in question).

Here, Dr. Ellkermann has applied no reliably objective standard for his opinions that the Prolift devices are safe and effective. Nowhere does Dr. Ellkermann or Ethicon identify any objective standard applied by Dr. Ellkermann, or by which Dr. Ellkermann's opinions can be tested or objectively evaluated. As such, he should be precluded from giving any opinions related to the adequacy of the design, safety, and efficacy of the mesh products.

Further, a major basis for his opinions on the Prolift is the peer reviewed literature, yet it is unknown what materials Dr. Ellkermann reviewed or did not review from his reliance list, including what medical literature he has reviewed and relied upon for his opinion.[30] As Dr. Ellkermann's testimony makes clear, his reliance list does not contain an accurate list of the facts or data considered by him in forming his opinions, as required by F.R Civ. P 26(a)(2)(B)(ii). Dr. Ellkermann testified that his reliance list contains materials that he did not actually review.[31] This violates F.R Civ. P 26(a)(2)(B)(ii)., and leaves Plaintiffs with an incomplete understanding

[29] Ellkermann Dep., Ex. B at 154:17 – 155:4.
[30] *Id*. at 41:15-23.
[31] *Id*.

of the facts and materials Dr. Ellkermann utilized to support his opinions. Given that Dr. Ellkermann's testimony indicates that he did not actually review or rely on any objective standard for his opinions regarding Prolift, and given that he relies on the clinical literature, yet did not disclose what literature and other materials he relied upon, an appropriate remedy is to disallow this opinion as provided in F.R Civ. P 37(c)(1).

CONCLUSION

For all of these reasons, this Court should preclude Dr. Ellkermann from giving any opinions about the Prolift or Gynemesh PS's product design, including but not limited to the opinions that the Prolift/Gynemesh PS are reasonably safe for their intended use, and that the benefits of the Prolift/Gynemesh PS outweigh the risks. Dr. Ellkermann's testimony indicates that he not qualified to discuss design issues, because he does not have the necessary "knowledge, skill, experience, training, or education" about the design process. *See* Fed. R. Evid. 702. Dr. Ellkermann did not review Ethicon's key design documents and demonstrated a lack of knowledge about that process generally. Therefore, Dr. Ellkermann does not possess "sufficient specialized knowledge to assist the jurors in deciding the particular issues in the case." *See Belk*, 679 F.3d at 162.

In addition, Dr. Ellkermann's failure to review the key design documents, so as to learn about the design of the product, as well as his reliance on complication rates that have not been produced, demonstrate that Dr. Ellkermann did not use a reliable methodology in forming his opinions. In other words, he does not have "good grounds" for his opinions on product design. *See Benedi*, 66 F.3d at 1383.

The Court should also exclude Dr. Ellkermann's warnings opinions. He admits that he is not familiar with the process by which a manufacturer creates its warnings, and his report lacks

any scientific analysis on warnings. Dr. Ellkermann's opinions should also be excluded because he has not disclosed the basis for his opinions.

Dated: October 18, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on October 18, 2018, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

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